

**REMARKS**

Claims 9-18 and 26-31 are pending after entry of the amendments set forth herein.

Claims 9-18 and 26-29 were examined. Claims 9-18 and 26-29 were rejected. No claims were allowed.

Claims 9 and 16 are amended. The amendments to the claims were made solely in the interest of expediting prosecution, and are not to be construed as an acquiescence to any objection or rejection of any claim. Support for the amendments to the claims are found in the claims as originally filed, particularly page 9, line 7, page 36, line 24, and page 4, lines 3-10, and throughout the specification. No new matter is added by these amendments.

Applicants respectfully request reconsideration of the application in view of the remarks made herein.

**Rejections under 35 U.S.C. § 112, second paragraph**

Claims 9-18 and 26-29 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that the applicant regards as the invention. The Applicants respectfully traverse these rejections.

Claim 9 is rejected as vague for reciting the term “Toso” because the full meaning of acronym should be spelled out as in its first use in a claim.

The Applicants respectfully submit that the term “Toso” is not an acronym. As discussed in the first paragraph of the Detailed Description of the Invention, starting on line 21 of page 8 of the specification, the term “Toso” is a Japanese word (not an acronym) that describes a liquor that is drunk on New Year's Day to celebrate long life and eternal youth. Since “Toso” is not an acronym, it cannot be spelled out. Accordingly, this rejection may be withdrawn.

Claim 9 is also rejected as vague because it is not clear what “Toso cell surface receptor” means.

Without wishing to acquiesce to this rejection, claim 9 is amended to recite “Toso protein”. Toso proteins are described the Detailed Description of the Invention, from page 8, line 21 to page 12, line 6 of the specification. Further, the claims limit the polynucleotides used in the method to only those that



will hybridize under high stringency conditions to SEQ ID NO:1. In view of the lengthy description of Toso proteins in the specification, and their relatedness to proteins encoded by SEQ ID NO:1, the Applicants respectfully submit that one of skill in the art would understand what is being claimed.

In view of the foregoing discussion, the Applicants respectfully submit that the term "Toso protein" in claim 9 is not vague. Accordingly, this rejection may be withdrawn.

Claim 9 is rejected as broad because it is not clear if the addition of a bioactive agent is done *in vitro* or *in vivo*.

Without wishing to acquiesce to this rejection, Claim 9 is amended to recite an "in vitro" method.

The Applicants respectfully submit that this rejection may be withdrawn.

Claim 9 is also rejected as vague and indefinite because it is not clear if the apoptotic agent will bind Toso receptor to induce apoptosis.

In making this rejection, the Applicants respectfully submit that the Office is requiring that the Applicants recite a mechanism of action of the apoptotic agents recited in the claim for the claim to be understandable. However, as is well established in the law<sup>1</sup>, an understanding of the precise scientific mechanism by which a process works is not essential for patentability. Accordingly this rejection may be withdrawn without any further discussion.

In other words, the precise scientific mechanisms by which apoptotic agents exert their effect and the precise scientific mechanisms by which Toso protects against apoptosis is not presently known. However, according to the law<sup>1</sup>, this should have no impact on the patentability of the instant claims. Accordingly, this rejection may be withdrawn.

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<sup>1</sup> *Philip Morris, Inc. v. Brown & Williamson Tobacco Corp.*, 641 F. Supp. 1438, 1483 n.13, 231 USPQ 321, 355 n.13 (M.D. Ga. 1986) , supplemental opinion, 645 F. Supp. 174 (1986) ("understanding of the precise scientific mechanism by which the process works is not essential to patentability because scientific principles and natural phenomena are not patentable")



Claim 10 is rejected as incomplete for omitting essential steps. The Office asserts that the claim fails to say where in the method of claim 9 the step of claim 10 occurs.

Without wishing to acquiesce to the correctness of this rejection, claim 10 has been amended. The Applicants respectfully submit that claim 10 does not omit essential steps, and meets the requirements of 35 U.S.C. 2<sup>nd</sup> paragraph.

Accordingly, this rejection may be withdrawn.

Claim 11 is rejected as indefinite because it is assertedly unclear when the labeling agents are added.

Without wishing to acquiesce to the correctness of this rejection, claim 11 has been amended. The Applicants respectfully submit that claim 11 is clear, and meets the requirements of 35 U.S.C. 2<sup>nd</sup> paragraph.

Accordingly, this rejection may be withdrawn.

Claim 12 is rejected as indefinite because it is assertedly unclear when the apoptotic and non-apoptotic cells are added.

Without wishing to acquiesce to the correctness of this rejection, claim 12 has been amended. The Applicants respectfully submit that claim 12 is clear, and meets the requirements of 35 U.S.C. 2<sup>nd</sup> paragraph.

Accordingly, this rejection may be withdrawn.

Claim 16 is rejected as indefinite because it is assertedly unclear because, according to the Office, "both Toso and the compound are each defined by each other".

The Applicants respectfully request that this rejection be explained in more detail or withdrawn, since the Applicants can see no evidence of both Toso and the compound being defined by each other in claim 16. On the contrary, since the term "Toso protein" is described throughout the specification (see above), and the term "compound" is a well-used, well-understood, dictionary-defined word, one of skill in the art would readily understand the meaning of the claim.

Accordingly, the Applicants respectfully submit that claim 16 is clear, and meets the requirements of 35 U.S.C. 2<sup>nd</sup> paragraph. This rejection may be withdrawn.



SUMMARY

Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number RIGL-002CON.

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Respectfully submitted,  
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